
Can a health care intervention be cost-effective but not affordable?

September 19, 2018

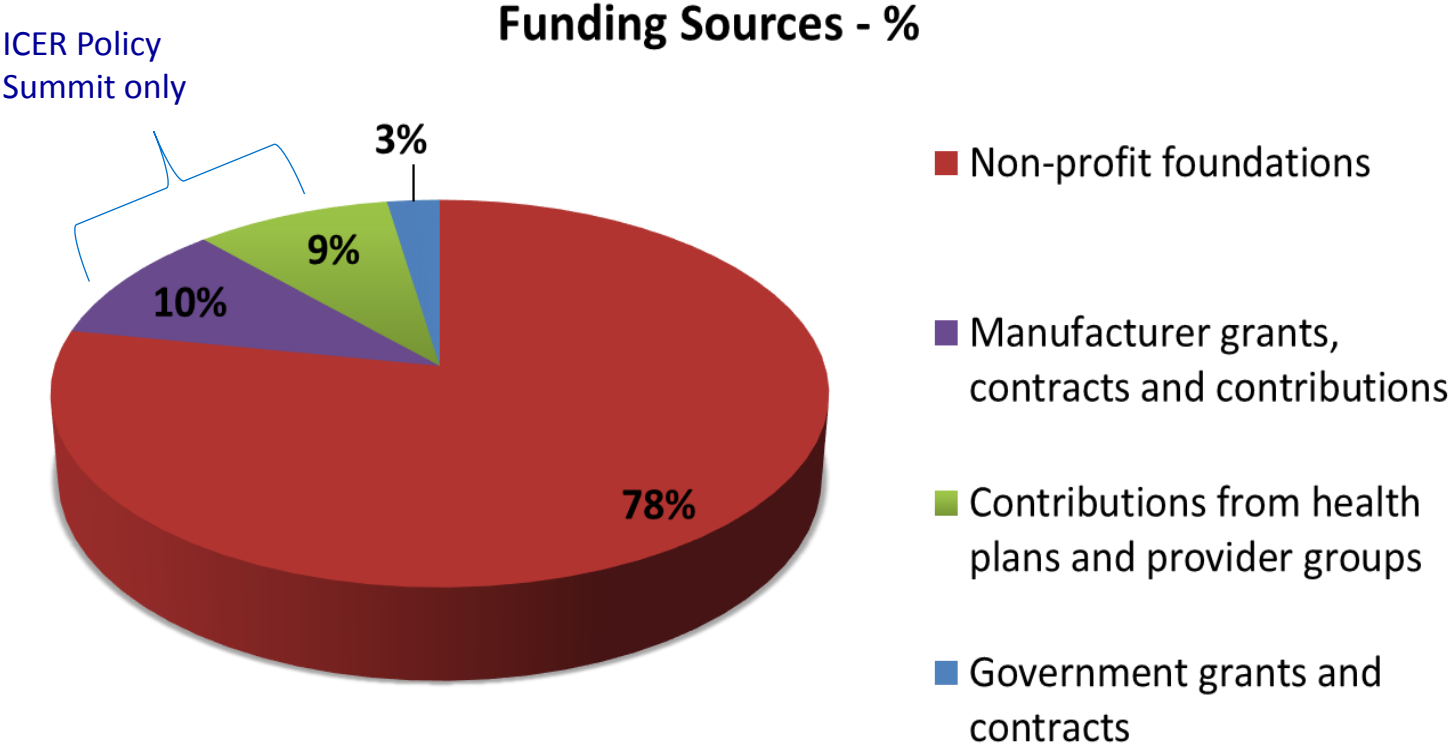


INSTITUTE FOR CLINICAL
AND ECONOMIC REVIEW

Institute for Clinical and Economic Review (ICER)

- **Independent** health technology assessment group whose reviews are funded by non-profit foundations
- Develop **publicly available value assessment reports** on medical tests, treatments, and delivery system innovations
- Use cost-effectiveness analysis to determine **value-based price benchmarks**
- Convene regional independent **appraisal committees** for public hearings on each report

Sources of Funding, 2018




Independent Appraisal Committees



CTAF
CALIFORNIA TECHNOLOGY
ASSESSMENT FORUM



MIDWEST
CEPAC
COMPARATIVE EFFECTIVENESS
PUBLIC ADVISORY COUNCIL



NEW ENGLAND
CEPAC
COMPARATIVE EFFECTIVENESS
PUBLIC ADVISORY COUNCIL

Use of ICER Assessments: Payers and Providers

- Medicaid programs
 - VA using ICER reports to negotiate prices
 - Private payers and PBMs
 - CVS new benefit design: “Reducing launch price using comparative effectiveness”
 - Drugs with a price that fails to reach a cost-effectiveness level of \$100K/QALY are a non-covered benefit
 - Newly launched drugs
 - Breakthrough drugs excluded
- (<https://cvshealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf>)

Poll Question #1: Pick one answer

- The closest approximation to the “right” price for new drug treatments that cure hepatitis C is:
 - A. The amount of money spent on research and development plus a “fair” profit
 - B. The price that results in an ICER below a WTP threshold of \$100-\$150K/QALY (2-3x per capita GDP/QALY)
 - C. The price that results in an ICER at some lower WTP threshold (e.g. 1x per capita GDP/QALY)
 - D. The price that would allow the health system within its current budget to pay for all patients to receive the treatment in a timely manner

“Cost-effectiveness” and “affordability”

- Positions

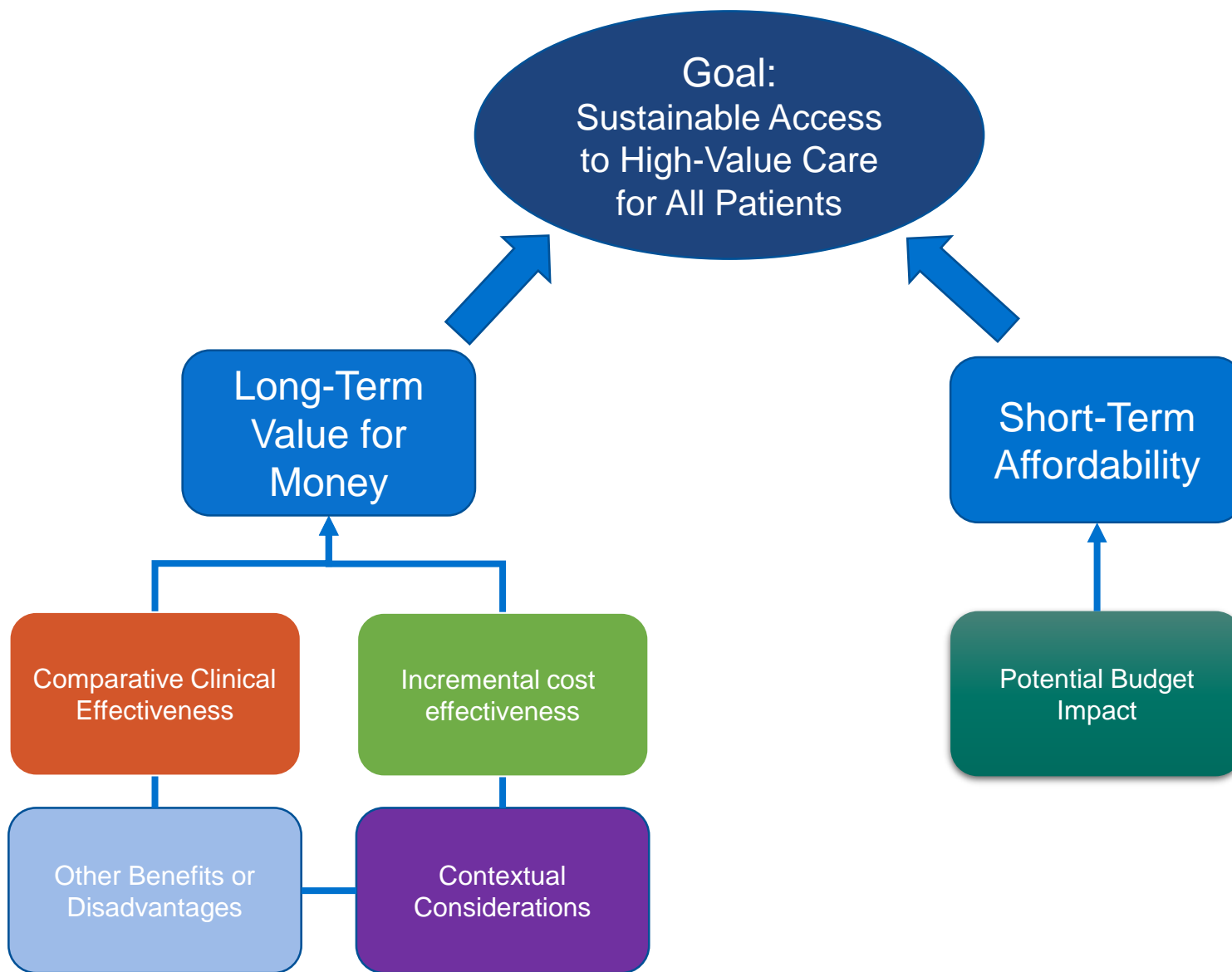
- The incremental cost-effectiveness ratio is useless to guide decisions regarding allocation of resources
- The WTP threshold is a good guide, full stop
- The WTP threshold is a good guide but it's too high
- The WTP threshold is a good guide to long-term value but blind to short-term affordability. Some integration of the two is needed to guide decision-making.

But what is “affordable”?

- Total resources available to spend?
- Opportunity cost: spending that will not...
 - Displace other services that yield higher health gains
 - Absorb new spending that could have spent on other services that would have yielded better health
 - Displace non-health spending that would yield better overall benefits to society
 - Create a rise in individual costs for health insurance that reduce access and lead to overall negative health impact

CEA and Affordability

- Options for integrating the two
 - Qualitative use of budget impact as one of many “contextual” factors
 - Quantitative use of budget impact to adjust the ICER
 - Quantitative use of budget impact to trigger unique funding conditions or other policy interventions



Potential Budget Impact and Affordability

- Policymaker interest in a potential budget impact “threshold”
 - Linked to rough judgment of opportunity cost by payers
 - Linked to some estimate of societal willingness to pay

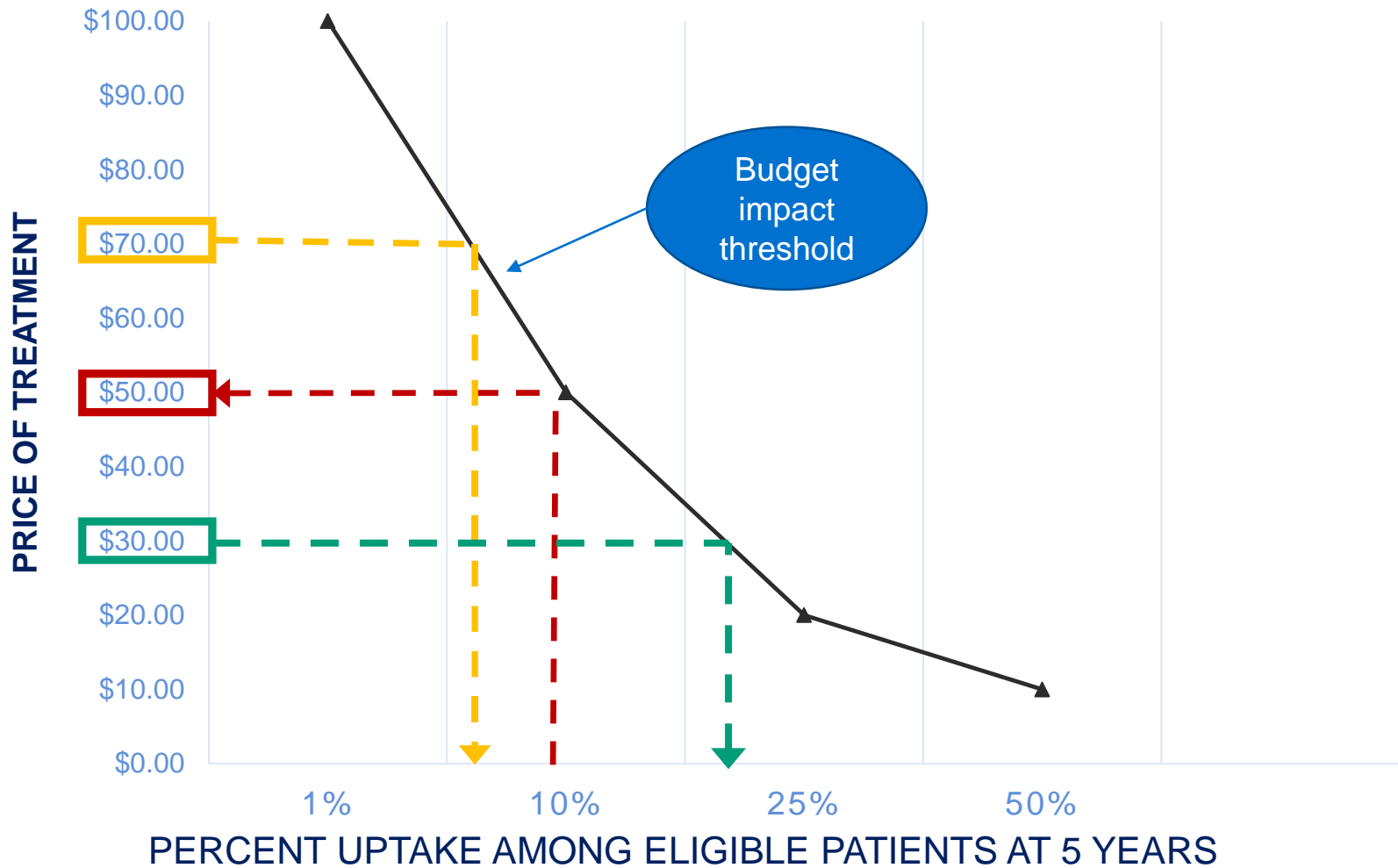
ICER Potential Budget Impact Threshold

- The purpose is to signal to stakeholders and policy makers when the amount of added health care costs associated with a new service – even one with good long-term value -- may be difficult for the health system to absorb over the short term without displacing other needed services or contributing to rapid growth in health care insurance costs that threaten sustainable access to high-value care for all patients.

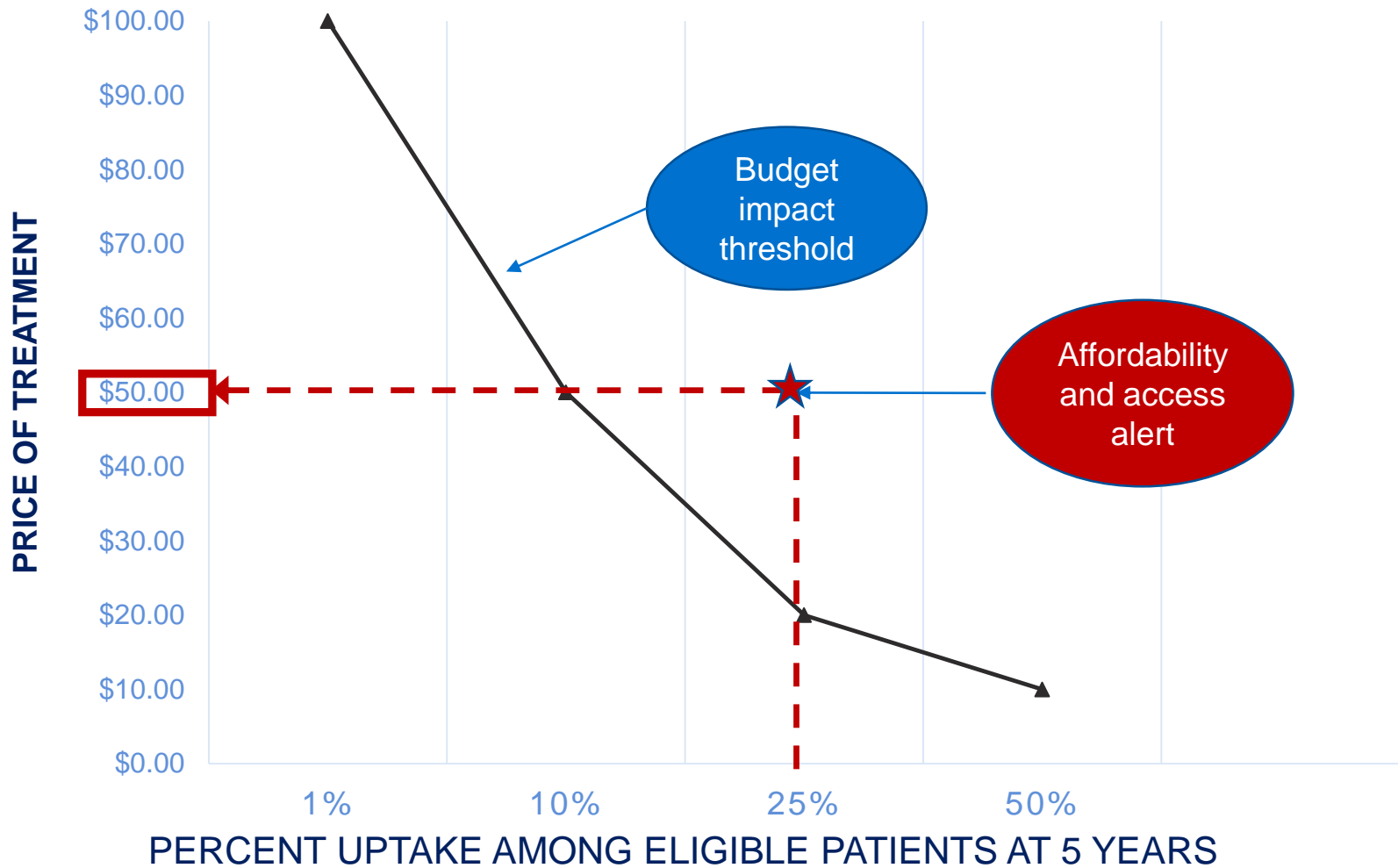
Potential Budget Impact threshold 2017-2018

Item	Parameter	2017-2018 Estimate	Source
1	Growth in US GDP, 2017 (est.) +1%	3.20%	World Bank, 2016
2	Total personal medical health care spending	\$2.71 trillion	CMS NHE, 2016
3	Contribution of drug spending to total health care spending	17.7%	CMS NHE, 2016; Altarum Institute, 2014
4	Contribution of drug spending to total health care spending	\$479 billion	Calculation (Row 2 x Row 3)
5	Annual threshold for net health care cost growth for ALL drugs	\$15.3 billion	Calculation (Row 1 x Row 4)
6	Average annual number of new molecular entity approvals	33.5	FDA, 2016
7	Annual threshold for average cost growth per individual new molecular entity	\$457.5 million	Calculation (Row 5 ÷ Row 6)
8	Annual threshold for estimated potential budget impact for each individual new molecular entity	\$915 million	Calculation (doubling of Row 7)

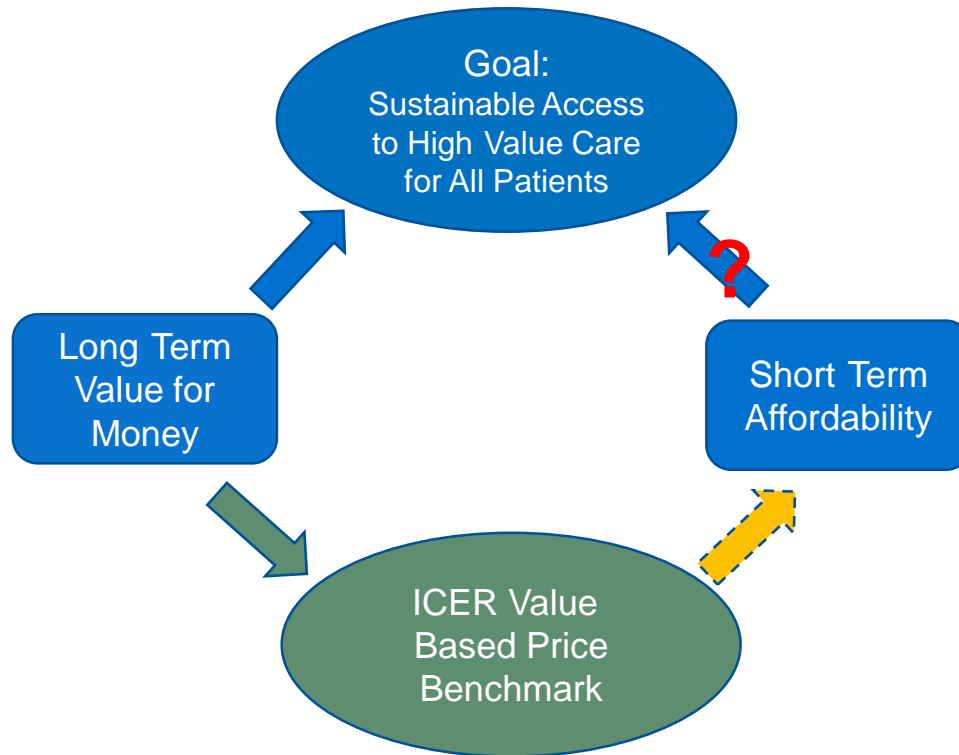
POTENTIAL BUDGET IMPACT SCENARIOS



POTENTIAL BUDGET IMPACT SCENARIOS



ICER value-based price benchmark



Tension between long-term value and short-term affordability?

	ICER < \$150K/QALY	Affordability “alert”
	Yes	Yes
	No	Yes
	Yes	Yes
	Yes	No
	No	No
	Yes	Yes
	Yes	Yes
	Yes	No
CAR-T for NHL	Yes	Yes
Endometriosis	Yes	Yes

How would an affordability threshold for the VA system be determined?

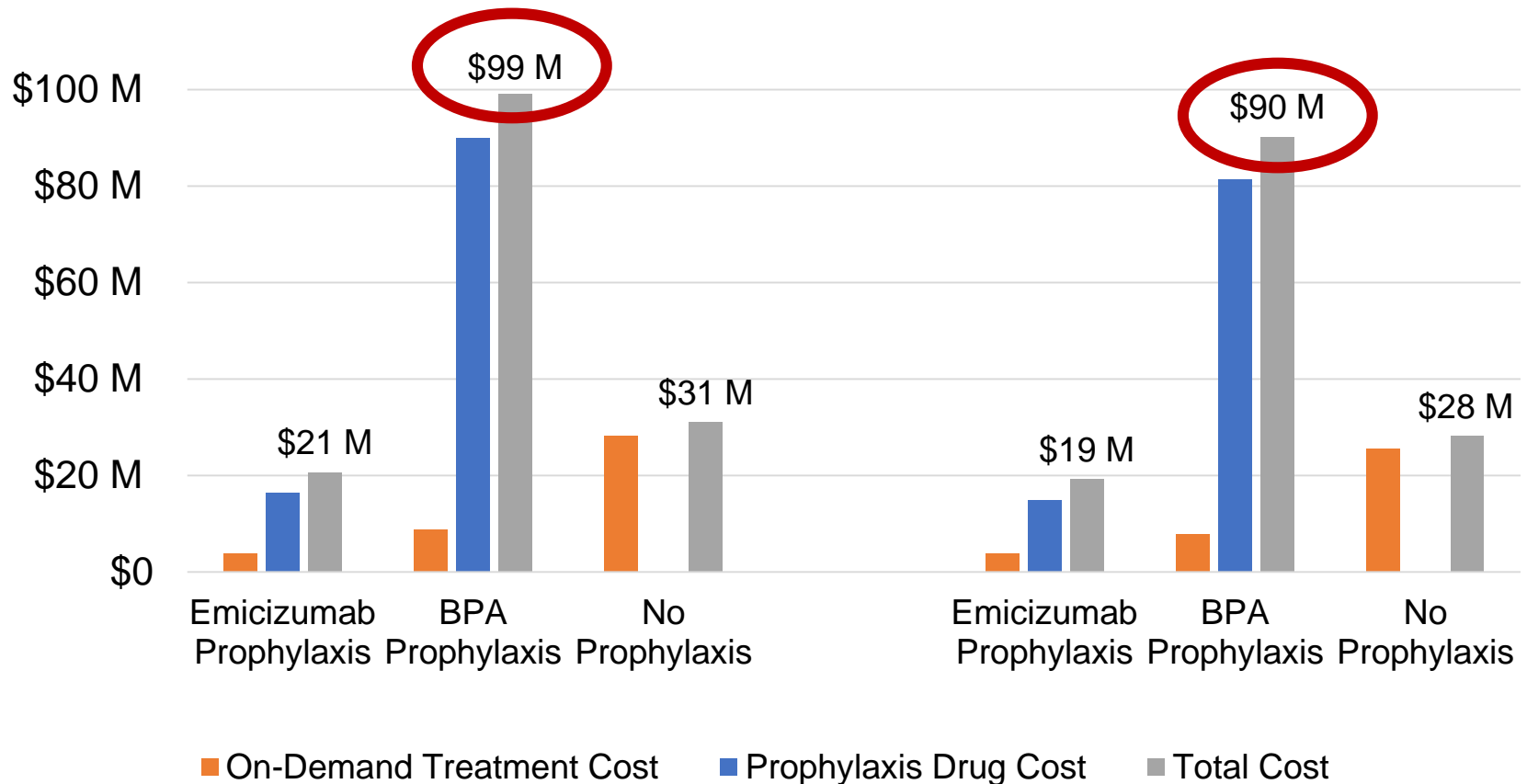
Poll Question #1: Select all that apply

- For which conditions is a genetic therapy “cure” expected to be available in the next 3 years?
 - A. Hemophilia A
 - B. Sickle-cell anemia
 - C. Spinal muscular atrophy
 - D. Muscular dystrophy

Special Challenges: Valuing a Cure

- *How should value-based prices for potential cures reflect magnitudes of lifetime health gains and cost offsets that are far beyond those ever generated by traditional therapies?*

Lifetime costs of Hemophilia A with need for bypassing agent (BPA) prophylaxis



What are the options for value-based pricing of cures?

- Full price at standard cost-effectiveness WTP thresholds -- untenable
- Price cap at WTP for QALY gain no matter what cost offsets
- “Shared savings”

Options for value-based pricing options of a cure

- New cure of a fatal disease of a 5 year-old child who would die in 10 years with standard Rx
- Assumed WTP threshold of \$100,000/QALY

	Cost per year of current Rx	QALY gained	QALY gain price	Cost offset price component	“Value based” price
Standard CEA	\$200,000	50	\$10 million	\$10 million	\$20 million
Price cap	\$200,000	50	\$10 million	\$0	\$10 million
Shared savings 50%	\$200,000	50	\$10 million	\$5 million	\$15 million
Shared savings 75%	\$200,000	50	\$10 million	\$2.5 million	\$12.5 million

Options for value-based pricing options of a cure

- New cure of a non-fatal chronic disease with utility gain of 0.2 per year for 50 years
- Assumed WTP threshold of \$100,000/QALY

	Cost per year of current Rx	QALY gained	QALY gain price	Cost offset price component	“Value based” price
Standard CEA	\$200,000	10	\$1 million	\$10 million	\$11 million
Price cap	\$200,000	10	\$1 million	\$0	\$1 million
Shared savings 50%	\$200,000	10	\$1 million	\$5 million	\$6 million
Shared savings 75%	\$200,000	10	\$1 million	\$2.5 million	\$3.5 million

Conclusion

- Cost-effectiveness analysis is but one component in determining how to allocate resources
- Affordability cannot be entirely subsumed in a single ICER
- For cures, should cost-effectiveness be abandoned completely or integrated with other pricing paradigms?
- How to manage the tension between long-term and short-term value perspectives is an important responsibility of every health system

Thank you